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**From:** Kausch, Jeannine [Kausch.Jeannine@epa.gov]  
**Sent:** 2/6/2017 8:02:23 PM  
**To:** Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]  
**CC:** Carlisle, Sharon [Carlisle.Sharon@epa.gov]  
**Subject:** Notice of Receipt for Wolbachia EUP Amendment and Extension - Draft  
**Attachments:** FR Notices for EUPs.pdf

Rick,

BPPD recently received an application to amend and extend the currently existing experimental use permit (EUP) for *Wolbachia pipientis*, wAlbB strain in *Aedes aegypti* mosquitoes (89668-EUP-3) from MosquitoMate, Inc. (MosquitoMate).

Here's a summary of what is currently approved and what MosquitoMate appears to be proposing:

(1) Current EUP

- Mosquito releases authorized in Fresno County (CA), Monroe County (FL), and Orange County (CA) to collect product performance data through the end of 2017.
- MosquitoMate rears and sorts the mosquitoes and ships them to the experimental sites.

(2) Proposed EUP

- Request to release mosquitoes in Fresno County (CA), Harris County (TX), Lee County (FL), and Miami-Dade County (FL) to collect product performance data through the end of 2018.
  - o Note: At this point, it is not clear if MosquitoMate is intending to not do/continue testing in Monroe County (FL) and Orange County (CA). This aspect of the proposal will need to be better explained.
- MosquitoMate rears and sorts some of the mosquitoes and ships them to some of the experimental sites.
- Verily Life Sciences, Inc., another company cooperating with MosquitoMate, rears and sorts some of the mosquitoes and ships them to the Fresno County (CA) experimental site.
  - o Note: New manufacturing process data package provided to explain and support this approach.

BPPD proposes to not publish a Notice of Receipt (40 CFR § 172.11(a)), given previous interpretation from our Office of General Counsel on publication requirements for EUPs (see attached). The regulation for Notices of Receipt for EUPs says the following:

"The Administrator shall publish notice in the FEDERAL REGISTER of receipt of an application for an experimental use permit upon finding that issuance of the experimental use permit may be of regional or national significance."

In reading this and applying the interpretation from OGC, we see two prongs for identifying whether an EUP requires a Notice of Receipt:

- (1) Would approval result in the EUP's issuance (i.e., the act of making something available for the first time)?
- (2) Would approval be of regional or national significance?

If you get a “No” to the first question, then you don’t continue to the second question and don’t need to do a Notice of Receipt. (In the case of the MosquitoMate’s *Wolbachia* EUP, one would get a “No” to the first question as you are not making something available for the first time and are amending/extending something that is already issued.) If there is uneasiness about saying “No” to the first question, then we believe that the amendment/extension, which continues to test in Florida and California and only expands into a small portion of one county in Texas, is not of regional or national significance.

Having said all of this, we did issue a Notice of Receipt for the previous 89668-EUP-3 amendment/extension at the request of the former Office Director in the interest of transparency. Out of 11 comments received (5 of which were negative), only two were substantive negative comments, one from a competitor company (Oxitec, Ltd.) and one from an individual associated with the competitor company.

Thanks,  
Bob